International Acceptance of In Vitro Alternative Ocular Safety Test Methods: Bovine Corneal Opacity and Permeability (BCOP) Test Method (draft OECD TG 437)

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The BCOP is an *in vitro* method that provides short-term maintenance of normal physiological and biochemical function of the bovine cornea. Potential ocular damage is assessed by changes in opacity and permeability to fluorescein. ICCVAM recommended that BCOP could be used to classify positive substances as ocular corrosives and severe irritants. While not a complete replacement for the *in vivo* rabbit eye test, BCOP can be used in a tiered-testing strategy for regulatory classification and labeling within a specific applicability domain. These recommendations were accepted by U.S. Federal agencies, and positive results from BCOP can be used in the U.S. instead of the rabbit eye test for making certain regulatory hazard classification decisions. To have the greatest impact on reducing animal use, ICCVAM, with stakeholders in the U.S., EU, and Japan, drafted an OECD Test Guideline (TG) that is based on the ICCVAM BCOP test method protocol. This protocol was developed following an international peer review evaluation with contributions from ECVAM and JaCVAM. Draft TG 437 was recently accepted by the OECD WNT. Once formally adopted by the OECD Council, all 30 OECD member countries in accordance with OECD Mutual Acceptance of Data will accept TG 437. Use of BCOP will reduce rabbit use for eye safety testing and eliminate such testing in animals of most substances likely to cause severe pain and discomfort. ILS staff supported by NIEHS contract N01-ES-35504. The views expressed above do not necessarily represent the official position of any government agency.